MAY 0 8 2014

5. 510(k) Summary or 510(k) Statement

5.1 510(k) Summary

Ref. to 21 CFR 807.92

1	Submitted by:	DDD-Diagnostic A/S Dr. Neergaards Vej 5E 2970 Horsholm, Denmark Tel: + 45 45 768888 Fax: + 45 45 164659
	Contact person:	Trine Olesen Tel: + 45 45 768888 Fax: + 45 45 164659 E-mail: trine.olesen@ddd-diagnostic.dk
	Preparation date:	November 25, 2013
2	Device Trade Name:	QuantumCam (Commercial name) (BodyMD is the development name)
	Common Name:	Gamma Camera System
	Classification name:	Emission computed tomography system
3	Predicate Device:	UNICORN MODEL SYS0630 (later renamed as Meridian), DDD-Diagnostic A/S
	510(k) Number:	K001888
4	Device description:	The QuantumCam is a general purpose dual detector gamma camera system comprised of a mechanical gantry allowing the Detectors to be positioned and moved in close proximity to the patient for scanning. The Gantry provides for positioning of the detectors in location(s) suitable for patient to be brought in position for tomographic, whole body scanning as well as planar scanning in sitting or standing position.

	Functional description:	The Detectors are standard NaI (Sodium Iodide) / Photomultiplier based scintillation detectors designed following the Anger Camera principles first described by Hal Oscar Anger. This detector technology has been used effectively in Nuclear Medicine for decades. The Detectors are equipped with standard Collimators following the principles known to the industry. The image data from the detectors are collected by hardware in the detector and the data acquisition is controlled by software running on a standard personal computer with a suitable operating system. The data may subsequently be transferred to a Nuclear Medicine Workstation for processing and interpretation. This Workstation is not part of the QuantumCam system.
5	Intended use:	The intended use of the QuantumCam gamma camera system is to perform general nuclear medicine imaging procedures. This is intended to be accomplished by imaging the distribution of a radiopharmaceutical within the human body. Gamma rays emitted from the radiopharmaceutical are detected by the gamma camera system and formed into images characterizing and showing the state of organs or structures in the form of functional images. When QuantumCam is connected to a nuclear medicine workstation, these images can be used in concert with other clinical data to assist in making clinical diagnoses by authorized medical personnel.. <u>Indications for use.</u> The QuantumCam is a gamma camera system designed to acquire data for whole body static, gated or dynamic and multi-slice images. The system is intended for use as diagnostic imaging device. When used with appropriate radio pharmaceuticals, images are produced representing the internal distribution of radioactivity in head or body. The system allows you to acquire data for high resolution three dimensional, static, gated or dynamic images of biochemical and metabolic processes using Tc-99m, Tl-201, I-123, In-111, Ga-67, Co-57.
6 a	Summary of technological characteristics:	The submitted device has the same technological and functional characteristics as the predicate device. However, the gantry with patient support device is in design different:

	Submitted device: QuantumCam, 9SYS2070	**Predicate device: Unicorn model, SYS0630**
Design:	The QuantumCam is an open gantry design supported on an open base frame. The complete system is comprised of: a gantry base, detector tower, detector gear box and two imaging detectors, collimator cart, PC, and electronics including a main PSU.	Lightweight compact casted aluminum ring gantry supporting a single detector in an unbalanced design. The complete gantry is comprised of: a ring gantry, a detector, a patient table, a collimator cart, PC, and electronics including a main PSU.
Material:	The QuantumCam employs detector of scintillation crystals in a traditional Anger design. The gantry and patient table employs steel and anodized aluminum, steel plate and aluminum covers.	The predicate device employs a traditional detector Anger design of scintillation crystals and PM tubes. The gantry employs casted and extruded aluminum, steel plate and fiberglass covers.
Energy source:	Mains supply. 200VAC – 240VAC	Mains supply. 100VAC – 240VAC
Detector:	The QuantumCam has two separate detectors. Each detector casting is supported by means of a U-shaped detector arm in a balanced design enabling manual tilt of the detector. The complete detector is comprised of: a detector casting, a NaI detector crystal, PM tubes, collimators and electronics for data processing.	The detector is supported by means of 2 casted aluminum brackets secured to the side of a gantry bearing by means of 2 linear bearings. The linear bearings enables radial detector positioning and detector tilt. The detector is a reinforced casted lead housing.

Software:	The QuantumCam acquisition station is based on a PC architecture with Windows 7 64bit operating system and Microsoft SQL for database handling. A dedicated S/W package for Graphic User Interface (GUI) - S/W package for acquisition setup and gantry/detector motion control. The package also includes means for data transmission via an external network.	The predicate device acquisition station is based on a PC architecture with Windows NT 4.0. SP 6+ operating system. The system is controlled by a software package formed by a dedicated Software (S/W) package for Graphic User Interface (GUI) and a dedicated S/W package designed for the purpose of controlling system setup, gantry/table motions and acquisition and data transfer.

6 b Description of how the non clinical test results have been collected:

Non clinical data has been obtained according to DDD quality system procedures as investigations performed according to standards as listed below, conducted and reported by qualified experts:

Specifications:	Intrinsic Spatial Resolution, FWHM, UFOV @ surface. ≤ ± 3.9 mm	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1:2007 in a 20% energy.
	Spatial Resolution, FWHM, LEGP collimator @ 10cm, Tc-99m. < 9.1 mm	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1:2007 in a 20% energy.
	Energy Resolution, @Tc-99m. ≤ 9.6 %	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1:2007 in a 20% energy.
	Spatial Linearity, UFOV, Diff. < ± 0.2 mm	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1:2007 in a 20% energy.

Flood Field Uniformity, UFOV Intrinsic, Diff. < ± 2.55 %	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1:2007 in a 20% energy.
Maximum Count rate with scatter. > 320 kcps	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1:2007 in a 20% energy.
Count rate Sensitivity, @ 20 % loss. > 225 kcps	Test equipment used, test setup and all calculations have all been performed according to the NEMA Standard NU 1:2007 in a 20% energy.
Detector shielding Sensitivity, @ 184 keV. < 2.0 %	The QuantumCam detector was mounted with a Medium Energy General Purpose collimator (MEGP). A Ga-67 source (184 keV) in source holder. Has been performed according to the NEMA Standard NU 1:2007 in a 20% energy.

Rationale for substantial equivalence:

The type of energy source applied is the same for the two devices. The QuantumCam has a limited power voltages range 200-240VAC whereas the predicated device has a range of 100-240VAC. This will in no way influence the safety or effectiveness of the QuantumCam system.
The two devices are therefore still considered substantial equivalent.

Conclusion:

The submitted device has been evaluated for effectiveness, electrical and mechanical safety, and has been found in compliance with applicable medical device standards, as referred to in Appendix 1. Based on this DDD considers the QuantumCam to be substantially equivalent in terms of safety and effectiveness to the predicate device, UNICORN MODEL SYS0630, K001888.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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DDD-Diagnostic A/S
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DENMARK

May 8, 2014

Re: K140206
Trade/Device Name: QuantumCam
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: April 22, 2014
Received: April 25, 2014

Dear Ms. Olesen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140206

Device Name: QuantumCam

Indications for Use:

The QuantumCam is a gamma camera system designed to acquire data for whole body static, gated or dynamic and multi-slice images. The system is intended for use as diagnostic imaging device. When used with appropriate radio pharmaceuticals, images are produced representing the internal distribution of radioactivity in head or body. The system allows you to acquire data for high resolution three dimensional, static, gated or dynamic images of biochemical and metabolic processes using Tc-99m, Tl-201, I-123, In-111, Ga-67, Co-57.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K140206